equipment and devices used in connection with the production, utilization or storage of special nuclear material.

[21 FR 764, Feb. 3, 1956. Redesignated at 25 FR 1607, Feb. 25, 1960, and 25 FR 12730, Dec. 13, 1960]

# § 70.59 Effluent monitoring reporting requirements.

Within 60 days after January 1 and July 1 of each year, and using an appropriate method listed in §70.5(a), each licensee authorized to possess and use special nuclear material for processing and fuel fabrication, scrap recovery, conversion of uranium hexafluoride, or in a uranium enrichment facility shall submit a report addressed: ATTN: Document Control Desk, Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, with a copy to the appropriate NRC Regional Office shown in appendix D to part 20 of this chapter. The report must specify the quantity of each of the principal radionuclides released to unrestricted areas in liquid and gaseous effluents during the previous six months of operation, and such other information as the Commission may require to estimate maximum potential annual radiation doses to the public resulting from effluent releases. If quantities of radioactive materials released during the reporting periods are significantly above the licensee's design objectives previously reviewed as part of the licensing action, the report must cover this specifically. On the basis of these reports and any additional information the Commission may obtain from the licensee or others, the Commission may from time to time require the licensee to take such action as the Commission deems appropriate.

[68 FR 58817, Oct. 10, 2003]

## Subpart H—Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material

Source: 65 FR 56226, Sept. 18, 2000, unless otherwise noted.

#### § 70.60 Applicability.

The regulations in §70.61 through §70.76 apply, in addition to other applicable Commission regulations, to each applicant or licensee that is or plans to be authorized to possess greater than a critical mass of special nuclear material, and engaged in enriched uranium processing, fabrication of uranium fuel or fuel assemblies, uranium enrichment, enriched uranium hexafluoride conversion, plutonium processing, fabrication of mixed-oxide fuel or fuel assemblies, scrap recovery of special nuclear material, or any other activity that the Commission determines could significantly affect public health and safety. The regulations in §70.61 through §70.76 do not apply to decommissioning activities performed pursuant to other applicable Commission regulations including §70.25 and §70.38 of this part. Also, the regulations in §70.61 through §70.76 do not apply to activities that are certified by the Commission pursuant to part 76 of this chapter or licensed by the Commission pursuant to other parts of this chapter. Unless specifically addressed in §70.61 through §70.76, implementation by current licensees of the Subpart H requirements shall be completed no later than the time of the ISA Summary submittal required in §70.62(c)(3)(ii).

### § 70.61 Performance requirements.

- (a) Each applicant or licensee shall evaluate, in the integrated safety analysis performed in accordance with §70.62, its compliance with the performance requirements in paragraphs (b), (c), and (d) of this section.
- (b) The risk of each credible high-consequence event must be limited. Engineered controls, administrative controls, or both, shall be applied to the extent needed to reduce the likelihood of occurrence of the event so that, upon implementation of such controls, the event is highly unlikely or its consequences are less severe than those in paragrahs (b)(1)-(4) of this section. High consequence events are those internally or externally initiated events that result in:
- (1) An acute worker dose of 1 Sv (100 rem) or greater total effective dose equivalent:

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- (2) An acute dose of 0.25 Sv (25 rem) or greater total effective dose equivalent to any individual located outside the controlled area identified pursuant to paragraph (f) of this section:
- (3) An intake of 30 mg or greater of uranium in soluble form by any individual located outside the controlled area identified pursuant to paragraph (f) of this section; or
- (4) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that:
- (i) Could endanger the life of a worker, or
- (ii) Could lead to irreversible or other serious, long-lasting health effects to any individual located outside the controlled area identified pursuant to paragraph (f) of this section. If an applicant possesses or plans to possess quantities of material capable of such chemical exposures, then the applicant shall propose appropriate quantitative standards for these health effects, as part of the information submitted pursuant to §70.65 of this subpart.
- (c) The risk of each credible intermediate-consequence event must be limited. Engineered controls, administrative controls, or both shall be applied to the extent needed so that, upon implementation of such controls, the event is unlikely or its consequences are less than those in paragraphs (c)(1)-(4) of this section. Intermediate consequence events are those internally or externally initiated events that are not high consequence events, that result in:
- (1) An acute worker dose of 0.25 Sv (25 rem) or greater total effective dose equivalent;
- (2) An acute dose of 0.05 Sv (5 rem) or greater total effective dose equivalent to any individual located outside the controlled area identified pursuant to paragraph (f) of this section;
- (3) A 24-hour averaged release of radioactive material outside the restricted area in concentrations exceeding 5000 times the values in Table 2 of Appendix B to Part 20; or
- (4) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that:

- (i) Could lead to irreversible or other serious, long-lasting health effects to a worker, or
- (ii) Could cause mild transient health effects to any individual located outside the controlled area as specified in paragraph (f) of this section. If an applicant possesses or plans to possess quantities of material capable of such chemical exposures, then the applicant shall propose appropriate quantitative standards for these health effects, as part of the information submitted pursuant to §70.65 of this subpart.
- (d) In addition to complying with paragraphs (b) and (c) of this section, the risk of nuclear criticality accidents must be limited by assuring that under normal and credible abnormal conditions, all nuclear processes are subcritical, including use of an approved margin of subcriticality for safety. Preventive controls and measures must be the primary means of protection against nuclear criticality accidents.
- (e) Each engineered or administrative control or control system necessary to comply with paragraphs (b), (c), or (d) of this section shall be designated as an item relied on for safety. The safety program, established and maintained pursuant to §70.62 of this subpart, shall ensure that each item relied on for safety will be available and reliable to perform its intended function when needed and in the context of the performance requirements of this section.
- (f) Each licensee must establish a controlled area, as defined in §20.1003. In addition, the licensee must retain the authority to exclude or remove personnel and property from the area. For the purpose of complying with the performance requirements of this section, individuals who are not workers, as defined in §70.4, may be permitted to perform ongoing activities (e.g., at a facility not related to the licensed activities) in the controlled area, if the licensee:
- (1) Demonstrates and documents, in the integrated safety analysis, that the risk for those individuals at the location of their activities does not exceed the performance requirements of paragraphs (b)(2), (b)(3), (b)(4)(ii), (c)(2), and (c)(4)(ii) of this section; or

(2) Provides training that satisfies 10 CFR 19.12(a)(1)–(5) to these individuals and ensures that they are aware of the risks associated with accidents involving the licensed activities as determined by the integrated safety analysis, and conspicuously posts and maintains notices stating where the information in 10 CFR 19.11(a) may be examined by these individuals. Under these conditions, the performance requirements for workers specified in paragraphs (b) and (c) of this section may be applied to these individuals.

# § 70.62 Safety program and integrated safety analysis.

- (a) Safety program. (1) Each licensee or applicant shall establish and maintain a safety program that demonstrates compliance with the performance requirements of §70.61. The safety program may be graded such that management measures applied are graded commensurate with the reduction of the risk attributable to that item. Three elements of this safety program; namely, process safety information, integrated safety analysis, and management measures, are described in paragraphs (b) through (d) of this section.
- (2) Each licensee or applicant shall establish and maintain records that demonstrate compliance with the requirements of paragraphs (b) through (d) of this section.
- (3) Each licensee or applicant shall maintain records of failures readily retrievable and available for NRC inspection, documenting each discovery that an item relied on for safety or management measure has failed to perform its function upon demand or has degraded such that the performance requirements of §70.61 are not satisfied. These records must identify the item relied on for safety or management measure that has failed and the safety function affected, the date of discovery, date (or estimated date) of the failure, duration (or estimated duration) of the time that the item was unable to perform its function, any other affected items relied on for safety or management measures and their safety function, affected processes, cause of the failure, whether the failure was in the context of the performance requirements or upon demand or both, and any correc-

- tive or compensatory action that was taken. A failure must be recorded at the time of discovery and the record of that failure updated promptly upon the conclusion of each failure investigation of an item relied on for safety or management measure.
- (b) Process safety information. Each licensee or applicant shall maintain process safety information to enable the performance and maintenance of an integrated safety analysis. This process safety information must include information pertaining to the hazards of the materials used or produced in the process, information pertaining to the technology of the process, and information pertaining to the equipment in the process.
- (c) Integrated safety analysis. (1) Each licensee or applicant shall conduct and maintain an integrated safety analysis, that is of appropriate detail for the complexity of the process, that identifies:
- (i) Radiological hazards related to possessing or processing licensed material at its facility;
- (ii) Chemical hazards of licensed material and hazardous chemicals produced from licensed material;
- (iii) Facility hazards that could affect the safety of licensed materials and thus present an increased radiological risk;
- (iv) Potential accident sequences caused by process deviations or other events internal to the facility and credible external events, including natural phenomena;
- (v) The consequence and the likelihood of occurrence of each potential accident sequence identified pursuant to paragraph (c)(1)(iv) of this section, and the methods used to determine the consequences and likelihoods; and
- (vi) Each item relied on for safety identified pursuant to §70.61(e) of this subpart, the characteristics of its preventive, mitigative, or other safety function, and the assumptions and conditions under which the item is relied upon to support compliance with the performance requirements of §70.61.
- (2) Integrated safety analysis team qualifications. To assure the adequacy of the integrated safety analysis, the analysis must be performed by a team